

ATTACHMENT A

REMARKS

Previous claims 20-39 have been canceled and are replaced herein by new claims 40-56. These claims do not include multiple dependency and it is believed that they define patentably over the prior art cited in the Final Rejection. Hence, immediate allowance of this application is respectfully requested.

The claims more clearly distinguish the present invention over the prior art. For example, independent claim 40 now recites that the liquid or gel introduced into the pouch is an accurate predetermined dosage and is in synchronous with the linear speed at which the strips are fed.

The prior claims were rejected as unpatentable over Davis in view of Sablotsky et al. The primary reference, Davis, relates to a totally different art, namely the food art. Specifically, Davis relates to the fast or convenience food industry, providing packages for condiments such as catsup or mustard or soups or sauces. The sophisticated dosing equipment required for the present invention is used only in the pharmaceutical industry, not the food industry. Not only is precision dosing a critical component of the finished product but it also has a cost saving and safety factor because (1) overloading with respect to a pharmaceutical drug is expensive and potentially dangerous so that one should never put in more than one needs for therapeutic effect, and (2) the volumetric units are measured in microliters, not millimeters, as with food/liquids for consumption.

It is also important that any gel injected does not get into the seal as this reduces the effective dose and can lead to premature delamination, thus reducing shelf-life.

Bearing in mind that most pharmaceutical patches are designed to last one to three years within a fixed temperature range, it is unlikely that any consumer food stuffs would be required to last this long and hence teachings in the food industry are not suggestive of the critical nature of filling pouches in the pharmaceutical field.

Moreover, any reduction in the integrity of the seal would cause the produce to perform outside of its extremely tight release specifications as required by regulatory authorities. Should the speed of the strip not be synchronized with the dosing process, the product could be rejected as being out of specification. Such results would never be a factor with respect to food products.

In light of the above, one of ordinary skill in the art would not look to Davis or any other patent in the food industry for teachings for filling packages in the pharmaceutical industry. The secondary patent to Sablotsky et al does relate to the pharmaceutical field. However, this patent was cited merely for the specific known feature of having multi-layers. This patent clearly does not provide sufficient teachings for modifying the primary reference which relates to the food industry for arriving at the present invention.

In view of the above, it is respectfully submitted that this application is now in condition for allowance, which action is promptly and respectfully solicited.

END REMARKS

ATTACHMENT B
Amendments to the Claims

Please cancel claims 20-39 without prejudice or disclaimer and add new claims 40-56 as set forth below.

This listing of claims will replace all prior versions, and listings, of claims in the application.

1-39. (Canceled)

40. (New) A continuous process for forming a transdermal patch, which comprises the steps of:

continuously feeding at a linear speed a first strip of materials comprising a disposable layer, a layer of adhesive and a layer of a permeable membrane;

continuously feeding in close proximity and in face-to-face relationship with the first strip at least one second strip formed of impermeable backing material(s), at the same linear speed;

passing the first and second strips together through a first sealing station at which at least the opposed longitudinal edge regions of the strips are secured together, optionally with intermediate regions of the strips being secured along their lengths, so as to form at least one elongate chamber;

passing the first and second strips joined at least at their longitudinal edges, through a second sealing station at which the strips are sealed to each other transversely at intervals along the strips, whereby the or each chamber becomes an open-topped pouch;

introducing an accurate predetermined dosage of a liquid or gel containing an active substance into the pouch or pouches, once formed, in synchronous with the linear speed; and

sealing the pouches along their previously open edges so as to form completely sealed pouches.

41. ⁼²¹ (New) A continuous process as claimed in claim 40, in which, at the second sealing station the previously open region of a pouch or pouches is sealed and the sealing simultaneously closes the adjacent region of the pouch or pouches immediately upstream of the first mentioned pouch or pouches.

42. ⁼²² (New) A continuous process as claimed in claim 40, further including a separation cutting step in which a transverse cutting exercise takes place so as to separate one sealed pouch containing the active substance from the adjacent pouches upstream and downstream.

43. ⁼²³ (New) A continuous process as claimed in claim 40, in which a "kiss-cut" function is provided at the separation cutting step.

44. ⁼²⁴ (New) A continuous process as claimed in claim 40, in which the two strips are first brought together and sealed along their longitudinal edges and separately or simultaneously one or more additional longitudinal seals are created intermediate the edge region seals thereby creating two or more laterally adjacent pouches across the width of the strips.

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45. (New) A continuous process as claimed in claim 44, in which the laterally adjacent pouches are separated in a longitudinal cutting step in which rollers, at least one of which has a cutting edge, act on opposite sides of the join strips, so as to separate the laterally adjacent pouches.

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46. (New) A continuous process as claimed in claim 40, further comprising a gas flushing step in which the or each pouch is flushed with gas during the step in which liquid or gel is introduced.

=27-29
47. (New) A continuous process as claimed in claim 46, in which in the gas flushing step, a small bore tube is placed adjacent a filling tube and flushing gas is ejected from the small bore tube directly into the pouch.

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48. (New) A continuous process as claimed in claim 40, in which the filling and sealing steps are effected at a pressure lower than atmospheric pressure.

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49. (New) A continuous process as claimed in claim 40, in which the sealing of adjacent strips is effected by opposing pairs of longitudinal or transverse sealing devices.

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50. (New) A continuous process as claimed in claim 49, in which the means by which the liquid or gel containing the active substance is introduced takes the form of a filling tube which is inserted into the ~~or each~~ pouch. ? typ.

=33
51. (New) A continuous process as claimed in claim 50, in which the lower end of the filling tube is at a level considerably below the axis of rotation of the sealing devices.

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52. (New) A continuous process as claimed in claim 50, in which the filling tube is positioned at a level just above where the transverse sealing devices are disposed.

=34
53. (New) A continuous process as claimed in claim 49, in which the filling tube is positioned at a level just above where the transverse sealing devices are disposed.

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54. (New) A continuous process as claimed in claim 49, further comprising the step of adjusting the number of pouches being produced side by side, by adding or removing one or more pairs of longitudinal sealing devices and adjusting the location of the intermediate sealing devices.

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55. (New) A continuous process as claimed in claim 49, further comprising the step of adjusting the size of the pouches, by adjusting the timing of transverse sealing devices, thereby changing the length of the pouches.

=37
56. (New) A continuous process as claimed in claim 40, in which the strips are fed in a substantially vertical direction and the liquid or gel containing an active ingredient is introduced into the pouch or pouches in a substantially vertical direction.